January 23, 2024

SurgMark GmbH
Christine König
CEO
Maria-Louisen-Straße 122
Hamburg, 22301
Germany

Re: K230836
Trade/Device Name: SchurSign Tissue Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: April 27, 2023
Received: December 12, 2023

Dear Christine König:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic.

See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2024.01.23 17:29:36 -05'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230836

Device Name
SchurSign Tissue Marker

Indications for Use *(Describe)*
Under supervision of a healthcare professional

• The SchurSign Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

Date Prepared:
January 22, 2024

I. SUBMITTER

Submitter of 510(k):

SurgMark GmbH
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D-22301 Hamburg Germany
+49 177 4075795 / info@surgmark.com
www.surgmark.com

Contact Person: Dr. Christine König
Christine.koenig@surgmark.com

II. DEVICE

Name of Device: SchurSign Tissue Marker

Common or Usual Name: Implantable Clip

Classification Panel: General and Plastic Surgery

Classification of the device: Class II, 21 CFR 878.4300

Product Code: NEU

III PREDICATE DEVICE

Primary Predicate:
Beacon (K130763)
Manufactured by Scion Medical Technologies, LLC

IV DESCRIPTION

SchurSign Tissue Marker consists of a radiographic soft tissue marker and a delivery system. SchurSign is a sterile, single patient use, discrete marker that is visible on standard radiographs (x-ray, mammography) as well as ultrasound, and Magnetic Resonance Imaging (MRI).

The proposed SchurSign Tissue Marker is placed into soft tissue during open, percutaneous, or endoscopic procedures to mark a surgical location.

The proposed SchurSign Tissue Marker is comprised of chitosan filled with Barium Sulfate.
The proposed SchurSign Tissue Marker delivery system is a distal delivery needle tip, rigid shaft, sterile, and single patient use preloaded delivery system incorporating the SchurSign Tissue Marker.
The delivery system consists of a cannula with a handle, a push rod with a plunger, and an end cap. The tissue marker is retained within the delivery system until placement is desired, where it is delivered through the end port by fully depressing the plunger into the handle. The SchurSign Tissue Marker delivery system is used to place the SchurSign Tissue Marker into soft tissue during open, percutaneous, or endoscopic procedures to radiographically mark a surgical location. The delivery system device has a bevelled 12 cm / 14 to 10 gauge needle with 1 cm depth marks and a plunger.

SchurSign is available in seven different sizes:

Model	Diameter (mm)	Length (mm)
SchurSign 1.5-5	1.5	5
SchurSign 1.5-8	1.5	8
SchurSign 2.0-5	2.0	5
SchurSign 2.0-8	2.0	8
SchurSign 2.0-10	2.0	10
SchurSign 2.5-10	2.5	10
SchurSign 3.0-10	3.0	10

V. INDICATIONS FOR USE

Under supervision of a healthcare professional (Rx)

- SchurSign Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

SchurSign has substantially equivalent indications to the Beacon Tissue Marker (K130763) in that they are indicated for use to mark soft tissue during a surgical procedure or for future surgical procedures.

SchurSign and Beacon are both made of polymeric material containing barium sulfate and have a cylindrical shape. Moreover, they are also sterilized by ethylene oxide.

Both SchurSign and Beacon have the same delivery system, which is a distal delivery needle tip, rigid shaft, sterile, and single patient use preloaded delivery system incorporating the marker. The delivery system consists of a cannula with a handle, a push rod with a plunger, and an end cap. The tissue marker is retained within the delivery system until placement is desired, where it is delivered through the end port by fully depressing the plunger into the handle. The SchurSign Tissue Marker delivery system is used to place the SchurSign Tissue Marker into soft tissue

during open, percutaneous, or endoscopic procedures to radiographically mark a surgical location.

The following table compares the SchurSign device to the predicate device with respect to intended use, material characteristics, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

DEVICE COMPARISON CHART

Parameter	Device	Primary Predicate Device	Equivalence
Trade name	SchurSign Tissue Marker	Beacon Tissue Marker	-
Company Name	SurgMark GmbH	Scion Medical Technologies, LLC	-
510(k) #	K230836	K130763	-
Product Code	NEU	NEU	Same
Indications For Use	The SchurSign Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.	The Beacon Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.	Same
Type of polymeric material	Chitosan	Oxford Performance Materials (OPM) OXPEKK-IG200	Different
Physical form	Cylinder	Cylinder	Same
Dimensions of tissue marker	Length: 5-10 mm, Diameter: 1.5-3.0 mm	Length: 5 mm, Diameter: 1.5 mm	Different
Is the marker for single use?	Yes	Yes	Same
X-ray contrast agent incorporated in the marker	Barium Sulfate	Barium Sulfate	Same
Sterilization Method	EO	EO	Same
Imaging modality	X-ray, mammography, ultrasound, and Magnetic Resonance Imaging	X-ray, mammography, ultrasound, and Magnetic Resonance Imaging	Same
Type of delivery system	Distal delivery needle tip, rigid	Distal delivery needle tip, rigid	Same

	shaft and sterile.	shaft and sterile.	
Dimensions of canula	Length: 12 cm Diameter: 14 – 10 gauge	Length: 12 cm Diameter: 14 gauge	Different
Components of the delivery system	Cannula with a handle, a push rod with a plunger, and an end cap	Cannula with a handle, a push rod with a plunger, and an end cap	Same
Material of canula	Stainless steel	Stainless steel	Same
Is the tissue marker already preloaded in the delivery system?	Yes	Yes	Same
Are the tissue marker and the delivery system sterilized together?	Yes	Yes	Same

The only difference between SchurSign and Beacon is the polymeric composition of the tissue marker and that SchurSign comes in different sizes. To prove that SchurSign is as safe and efficacious as its predicate device, a series of tests were done as shown below.

VII. PERFORMANCE DATA

In vitro - Performance data were provided in support of the substantial equivalence determination. The characteristics of the SchurSign Tissue Marker were substantially equivalent to the predicate device. SchurSign is equivalent to Beacon in an ex vivo test of ultrasound imaging of chicken breast.

In vivo - A swine study was done where x-ray and ultrasound were used to localize SchurSign. Histopathology was also conducted. The animal study showed that the performance of SchurSign was equivalent to its predicate device.

Biocompatibility testing

In vitro and *in vivo* tests:

To demonstrate that SchurSign is biocompatible, the following tests were done in accordance with ISO standards:

1) Cytotoxicity – according to ISO 10993-5
2) Acute systemic toxicity – according to ISO 10993-11
3) Sensitization – according to ISO 10993-10
4) Irritation – according to the ISO 10993-23

5) Subacute toxicity – according to ISO 10993-11
6) Implantation – according to ISO 10993-6
7) Pyrogenicity – according to USP-NF 2021
8) Genotoxicity – according to ISO 10993-3
9) Chemical characterization - according to ISO ISO 10993-18

Chronic toxicity and carcinogenicity endpoints were addressed through chemical characterization and toxicological risk assessment. It was concluded that neither the components nor potential leachables of SchurSign are of risk for the patient.

Test	Result
Cytotoxicity	The test article extract showed no cytotoxic potential to L-929 mouse fibroblast cells.
Acute systemic toxicity	There was no mortality or evidence of systemic toxicity from the extracts injected into mice.
Sensitization	The topical application of the SC and SO extracts did not induce delayed sensitization in the guinea pig. The test article was not considered a sensitizer.
Irritation/Intracutaneous reactivity	The test article met the requirements of the test since the difference between each test extract overall mean score and corresponding control blank overall mean score was 0.0 for the SC and SO test extracts.
Subacute toxicity	There was no evidence of systemic toxicity from the test article 4 weeks following subcutaneous implantation in the rat.
Implantation	The macroscopic reaction was not significant as compared to the negative control article. Microscopically, the test article caused a moderate reaction as compared to the negative control article.
Pyrogenicity	The test article met the requirements of the US Pharmacopoeia and was judged as non-pyrogenic.
Genotoxicity	The SC and DMSO test article extracts were considered to be non-mutagenic in the bacterial reverse mutation study.

VIII. CONCLUSIONS

The SchurSign Tissue Marker to be distributed by SurgMark GmbH is substantially equivalent in design and function to Beacon Tissue Marker (K130763) manufactured by Scion Medical Technologies, LLC. The subject device has the same intended use and similar characteristics and functional properties as the predicate device. Moreover, documentation supplied in this submission demonstrates that any differences in their technological characteristics or materials do not raise any new questions of safety or performance, and that the non-clinical data for the device supports the safety of the device.